



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-22-0010; Docket No. CDC-2022-0030]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS). Data from BD-STEPS will play an important part in the decision-making process that determines federal research agendas, birth defect prevention activities, and the direction of funding programs such as cooperative agreements.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0030 by either of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of

information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Birth Defects Study to Evaluate Pregnancy exposures (BD-STEPS)

(OMB Control No. 0920-0010, Exp. 2/28/2023) - Extension -

National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Birth defects are associated with substantial morbidity and mortality in the United States. About one in every 33 babies is born with a birth defect. Birth defects contributed to more than one million hospital stays in the U.S. in 2013, resulting in \$22.9 billion in hospital costs. Birth defects are the leading cause of infant mortality and the fifth leading cause of loss of potential years of life before age 65. One in five infant deaths is due to birth defects.

For most birth defects, the causes are not known, making prevention efforts challenging to develop. However, to date, primary preventive measures are available for only a few birth defects. For example, vaccination programs have reduced the incidence of congenital rubella syndrome, Rh hemolytic disease of the newborn can be prevented by appropriate medical practices, and genetic counseling can provide parents with information about the increased risk of Down syndrome associated with advanced maternal age. Perhaps most importantly, folic acid intake before and during pregnancy can prevent many cases of fatal or permanently disabling neural tube defects such as anencephaly and spina bifida.

This continued burden justifies reasonable attempts to reduce the prevalence of birth defects. To help reduce birth defects among U.S. babies, in 1996 Congress directed the CDC to

establish Centers of Excellence for Birth Defects Research and Prevention. The mandate was formalized with passage of the Birth Defects Prevention Act of 1998. The Act amended Section 317C of the Public Health Service Act (42 U.S.C. 247b-4) and authorized CDC to (1) collect, analyze, and make available data on birth defects; (2) operate regional centers that will conduct applied epidemiological research for the prevention of birth defects; and (3) provide the public with information on preventing birth defects.

In response to this mandate, the Division of Birth Defects and Infant Disorders (DBDID) obtained OMB clearance for data collection that is carried out by the Centers for Birth Defects Research and Prevention (CBDRP). The CBDRP's first research effort was the National Birth Defects Prevention Study (NBDPS), which began data collection in 1997 and ended in 2013. The CBDRPs transitioned from NBDPS to the Birth Defects Study To Evaluate Pregnancy exposures (BD-STEPS), which began data collection in 2014. One of the main activities for each Center is to conduct BD-STEPS in their state.

BD-STEPS is made up of a number of information collection activities. The interview is estimated to take approximately 55 minutes and is titled "Birth Defects Prevention Study: Computer Assisted Telephone Interview." For the five Centers not participating in the stillbirth component of the study, a maximum of 370 interviews are planned per year per center, 270 cases and 100 controls; for the two Centers participating in

additional stillbirth interviews, 590 interviews are planned per Center, 270 cases with birth defects, 100 controls, and 220 stillbirths without birth defects. With seven Centers and a maximum of 3,030 interviews, the maximum interview burden for all Centers combined would be 2,778 hours per year. The 55-minute burden includes the time for the telephone consent script which is reviewed with the mother at the beginning of the call to collect the information via the computer assisted telephone interview (CATI).

Five of the seven BD-STEPS Centers request consent for retrieval of leftover newborn bloodspots. If a maximum of 2,590 interviews would be expected for seven Centers (not including interviews of stillbirths without birth defects), a maximum of 1,850 would be expected for five Centers requesting consent for retrieval of leftover newborn bloodspots (excluding stillbirths, for which newborn bloodspots are not available). A maximum of 15 minutes would be expected for the participant to read the bloodspot retrieval consent request and sign the consent form. The anticipated maximum burden for bloodspot consent would be 463 hours annually.

With a maximum of 2,590 interviews planned annually (not including interviews of stillbirths without birth defects since they are not eligible for the online questionnaire), and approximately one-third of the respondents eligible for the online questionnaire (selected based on reporting occupations queried in the questionnaire), a maximum of 830 women would

receive the online questionnaire. Completion of the online questionnaire is estimated to take 20 minutes including reading introductory communication. The anticipated maximum burden for the online questionnaire is 277 hours annually.

CDC requests the release of reportable infectious diseases information from all women who complete the CATI except for women who experienced a stillbirth without a birth defect. A maximum of 2,590 women would receive the infectious disease information request. Based on experience with consent forms, we expect the review, signing and mailing of the release of reportable infectious diseases information to take a maximum of 15 minutes for participants. The anticipated maximum burden for the reportable infectious diseases information is 648 hours annually.

In the two Centers participating in the supplemental interview, mothers of infants with or without birth defects that are stillborn and controls are asked to participate in a supplemental telephone interview. The 25-minute supplemental interview includes the time for informed consent. Based on a maximum of 640 women to be interviewed with the supplemental questionnaire, the maximum burden time would be 267 hours annually.

Although participation rates may vary, the total estimates of annual burden hours for all activities, all individuals, and all Centers is 4,433 hours. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Mother's Interview	Telephone Consent Script/BD- STEPS Computer Assisted Telephone Interview	3,030	1	55/60	2,778
Mother's Consent for Bloodspot Retrieval	Consent for bloodspot retrieval	1,850	1	15/60	463
Mother's Online Occupational Questionnaire	Online Occupational Questionnaire	830	1	20/60	277
Mothers Infectious Disease Release Review	Infectious Disease Request Form	2,590	1	15/60	648
Mothers of AR/MA Stillbirths and Controls (Supplemental Telephone Interview)	Telephone Consent and Supplemental Interview	640	1	25/60	267
Total					4,433

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